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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,980	07/17/2000	RICHARD KOLESNICK	D6049	6671

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EXAMINER
HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
1647	9

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary

Application No.	Applicant(s)
09/554,980	FUKS et al.
Examiner	**Art Unit**
Fozia Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 17, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-7 and 10* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-7 and 10* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Receipt of Applicant's arguments and amendments filed in Paper No.8, 12/17/01 is acknowledged..

Claims 1-7 and 10 are pending and under consideration by the Examiner.

2. The following previous rejections and objections are withdrawn in light of Applicants amendments filed in Paper No.8, 12/17/01:

(i) The objection to the specification for not cross referencing prior Applications.

(ii) The objection to the specification for not containing an abstract.

(iii) The rejection of claims 4-7 under 35 U.S.C §112, second paragraph for reciting "characterized".

3. Upon further search and examination the indicated allowability of claims 1-3 and 10 is withdrawn. Rejections based on the newly cited reference follow.

Claim rejections-35 U.S.C. § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a pathophysiological state in an animal, wherein said pathophysiological state results from an increase in generation of ceramide from sphingomyelin which induces endothelial apoptosis said method comprising the step of administering b-FGF to said animal, does not reasonably provide enablement for a method of treating a pathophysiological state

such as autoimmune disease, by administering b-FGF to an animal suffering from an autoimmune disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Instant invention is drawn to a method of treating pathophysiological state in an animal, wherein said pathophysiological state results from an increase in generation of ceramide from sphingomyelin which induces endothelial apoptosis by administering b-FGF to said animal, and claim 5 further limits the invention to "a method of treating sepsis, radiation damage, autoimmune disease and acute respiratory distress by administering b-FGF to an animal suffering from said disease", however, "autoimmune disease" encompasses many disparate disorders, such as HIV, Lupus, rheumatoid arthritis and Alzheimer disease to name very few. Instant specification as filed does not disclose a single example where "an autoimmune disease" is treated by administering b-FGF to an animal suffering from said condition. Thus, the specification is non-enabling for a method of treating an autoimmune disease by the administration of b-FGF. By application of the factors set forth in In re Wands, page 1404, the factors which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, in the instant application, the quantity of experimentation to determine if administering b-FGF to an animal would treat an animal from all the diseases that arise from and directed against the individual's own tissues, is infinite with no guidance provided by Applicants. Furthermore, at the

time of the filing of this application, the art is silent and it is unpredictable whether administering b-FGF to an animal would result in treating autoimmune disease from said animal. Thus, Applicants are non-enabling for a method to treating a pathophysiological state in animal, wherein said pathophysiological state is selected from autoimmune disease, by administering b-FGF to said animal.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claims 1, 4 and 10 are vague and indefinite for reciting "pharmacologically effective dose....", because it is unclear what is the expected "pharmacological effect". Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuks et al (1994). Fuks et al a method of inhibiting radiation-induced programmed cell death *in-vitro* and *in-vivo* by administering basic fibroblast growth factor (b-FGF). The researchers using C3H/HeJ

mice exposed to lethal dose of whole lung irradiation which exhibited similar apoptotic changes in the endothelial cell lining of the pulmonary microvasculature within 6-8 hours of radiation exposure, showed that b-FGF given intravenously immediately before and after irradiation inhibited the development of apoptosis in these cells and protected mice against development of lethal radiation pneumonitis, (see abstract, pages 2585-2586, column 2 and figure 7). The researchers demonstrate that the radiation protection associated with b-FGF stimulation is not mediated via an effect on the repair of DNA breaks but rather through inhibition of interface apoptosis, (bottom of column 2 of page 2582 and top of column 1 of page 2583). Fuks et al suggest that radiation activation of membrane protein kinase C (PKC) or its activation by growth factors may play important role in the homeostatic control of radiation resistance in many cell types, (page 2588, column 2).

Claim 1 of the instant application is interpreted as being drawn to a method of administering an effective dose of b-FGF to an animal in need of treatment. Claims 4 and 5 further limit the invention to an animal which needs treatment from the induction of endothelial apopotosis. Fuks et al reference anticipates instant claims 1, 4-5, because this reference teaches the administration of b-FGF to a mammal, said mammal is exposed to lethal dose of radiation, therefore, it is in need of treatment from radiation induced apoptosis. The administration of b-FGF would inherently lead to the inhibition of ceramide generation from sphingomyelin, because a product's function is an inherent property of its structure.

Conclusion

No claim is allowable.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Mondays and Thursdays and every other Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary kunz can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
14 February 2002

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